510(k) SUMMARY

Porous HDPE Surgical Implants

K022565

OCT 09 2002

ePor, Inc.
731 1/2 N. LaBrea Avenue
Los Angeles, CA 90038
Tel: (323) 549-3831, Fax: (323) 549-3834

CONTACT

Eric V. Hohenstein
Tel: (323) 549-3831
Fax: (323) 549-3834

NAME OF DEVICE

Trade Name: Porous HDPE Surgical Implants, to be distributed under various trademarks including ePor, Biopor, Minopor, and p-HDPE.

Common Name: Preshaped porous polyethylene implants suitable for implantation into cranial and facial areas.

DEVICE CLASSIFICATION

NOMENCLATURE	CLASS NO.	CLASS	REG NO.
POLYMER ENT SYNTHETIC, POROUS POLYETHYLENE	77JOF	II	874.3620
PROSTHESIS, CRANIOFACIIAL	84JBA	II	882.5330
IMPLANT, MALAR	79LZK	II	
PROSTHESIS, EYE, INTERNAL	86FWO	II	886.3200
PROSTHESIS, FACIAL, MANDIBULAR IMPLANT	77JAZ	II	874.3695
PROSTHESES/NASAL DORSAL IMPLANT	79ESR	II	878.3680
PROSTHESIS, MAXILLA	77JCS	II	
PROSTHESIS, MAXILLOFACIAL	77LGK		
PROSTHESIS, NOSE, NTERNAL	79FZE	II	878.3680
PROSTHESIS, OTOPLASTY	77ESY	II	878.3590

STATEMENT OF SUBSTANTIAL EQUIVALENCE

ePor, Inc. Porous HDPE Surgical Implants are substantially equivalent to the Medpor® Surgical Implant Material; Preformed Cranial and Facial Implants K922489, based on the subject devices' similarity to the predicate devices in intended use, material, design, and surgical procedure.

INDICATIONS FOR USE

ePor, Inc. Porous HDPE Surgical Implants in block, sheet, and anatomical shapes are intended for the augmentation or reconstruction of the craniomaxillofacial skeleton.

DESCRIPTION

ePor, Inc. Porous HDPE Surgical Implants in block, sheet, and anatomical shapes are manufactured of porous high density polyethylene (HDPE), a material that has been used in craniofacial reconstruction for over 25 years.

Porous polyethylene is recognized as acceptable for implantation purposes through the folowing device classification per 21 Code of Federal Regulations.

	CLASS NO.	CLASS	REG NO.
POLYMER ENT SYNTHETIC, POROUS POLYETHYLENE	77JOF	II	874.3620

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 9 2002

Mr. Eric Hohenstein
ePor, Inc.
731 ½ N. LaBrea Avenue
Los Angeles, California 90038

Re: K022665
Trade/Device Name: Porous HDPE Surgical Implants
Regulatory Number: 21 CFR 878.3500
Regulation Name: Polytetrafluoroethylene with Carbon Fibers Composite Implant Material
Regulatory Class: II
Product Code: KKY
Dated: August 6, 2002
Received: August 9, 2002

Dear Mr. Hohenstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

APPLICANT: ePor, Inc.

510(k) NUMBER: (if known): K022665

DEVICE NAME: Porous HDPE Surgical Implants

INDICATIONS FOR USE:

Porous HDPE Surgical Implants in block, sheet, and anatomical shapes are intended for the augmentation or reconstruction of the craniomaxillofacial skeleton.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022665

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional